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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,632	04/02/1999	NATHANIEL T. BECKER	GC530-2	3949

5100 7590 09/26/2003

GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER
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TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 09/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

*Supplement*  
**Advisory Action**

Application N .

09/285,632

Applicant(s)

BECKER ET AL.

Examiner

Susan Tran

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal:  
2. ☐ The proposed amendment(s) will not be entered because:  
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 22-27, 41, 42, 46-48, 50-56, 58, 76 and 77.

Claim(s) withdrawn from consideration: 57 and 59-75.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

### **ATTACHMENT**

Applicant's arguments filed 08/08/03 have been fully considered but they are not persuasive.

The examiner is having trouble understand applicant's arguments regarding to the 103(a) rejection under Oshlack et al. US 5,639,476. The Office Actions dated 11/18/02 and 06/09/03 disclosed a 103(a) rejection over Oshlack et al. US 5,356,467.

Applicant alleges that the examiner has disregarded the Declaration and the starch literature submitted with the last amendment. Contrary to the applicant's argument, in the final office action dated 06/09/03, the examiner stated "The Declaration under 37 CFR 1.132 filed 04/12/03 has been fully considered, but is insufficient to overcome the rejection of claims 22-27, 41, 42, 46-48, 50-56, 58, 76, and 77 based upon Oshlack et al. US 5,356,467 as set forth in the last Office action because it does not provide a side by side comparison of the claimed invention and those of Oshlack to support the statement "adding hydrophobic acrylic polymer would result in loss of the rapid release". There was no data or experiment in the Declaration showing the coating containing 0.1% hydrophobic acrylic polymer in combination of water-soluble rate-controlling agent, erosion promoting agent, or pore-former that would result in loss of the rapid release. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness."

Applicant argues that the controlled release coating of Oshlack by definition cannot rapidly dissolve in use because a coating could not provide "controlled release" of anything. In response to applicant's argument that the reference does not show certain feature of applicant's invention, it is noted that the feature upon which applicant relies (i.e., rapidly dissolve coating) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant claims and specification do not disclose, mention, or require the invention to be a rapid dissolve coating; nor applicant claims exclude the coating to be a "control coating".

Applicant argues that all of the present claims distinguish over Oshlack since all embodiments of Oshlack require a water insoluble polymer. Applicant further alleges that Oshlack's release rates are delayed release. Contrary to the applicant's argument, applicant's claims do not exclude the coating from "controlled release", "sustained release", or "delayed release". The time release being argued in page 3 of applicant's remarks is irrelevant with respect to the scope of the claims. Although Oshlack teaches the use of water insoluble polymer, applicant has not provide data showing detrimental effect in the present of the present of the water-insoluble polymer in such a small amount 0.1% (column 3, line 56). Oshlack recognizes the advantageous results in obtaining a predetermined controlled release rate, or a selected desire release rate by adding a rate-controlling agent, erosion promoting agent, and release modifying passageways forming (column 4, lines 64 through column 5, lines 1-13). Thus, it is the

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position of the examiner that it would have been obvious for one of ordinary skill in this art to, by routine experimentation determine a suitable amount of water-soluble rate-controlling agent, erosion promoting agent, or pore-forming agent to obtain a desirable release/dissolution rate.

Applicant alleges that "the examiner's citation of column 3, line 56 of Oshlack et al. (page 5 of the Office Action) is not understood by applicants and does not appear to bear upon the issue. Column 3, line 56 is "after exposure to accelerated storage conditions. Clearly 0.1% hydrophobic polymer is not taught by Oshlack". Contrary to the applicant's argument, applicant's attention is called to the Office Actions, under the 103(a) rejection dated 11/18/02 and 06/09/03, the Oshlack patent that was cited is Oshlack '467. Clearly, Oshlack '467 at column 3, lines 55-56 disclose the percent amount of zein (hydrophobic polymer) can be as little as 0.1%.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235

  
THURMAN K. PAGE  
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